

B' (e) carriers as well as conventional vehicles for one or more of (a) to (d).

9. A kit according to claim 8, wherein the CREM-dependent proteins are selected from the group consisting of proacrosin, protamine, Tp-1, MCS, RT7, and combinations thereof.

REMARKS

Entry of the foregoing, reexamination and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

By the present amended, claims 1-4 have been canceled, without prejudice or disclaimer to the subject matter disclosed therein. New claims 5-9 have been added. Support for new claim 5 may be found, at the very least, in original claims 1 and 3, and at page 3, last paragraph, to page 4, first paragraph, of the specification as filed. Support for new claim 6 may be found, at the very least, at page 4, last paragraph, of the specification as filed. Support for new claim 7 may be found, at the very least, in original claim 2. Support for new claim 8 may be found, at the very least, in original claim 3. Support for new claim 9 may be found, at the very least, in original claim 4. No new matter has been added by the present amendment.

Objection of Claims 1, 2 and 4

Claims 1, 2 and 4 have been objected to for various informalities. Claims 1, 2 and 4 have been canceled by the present amendment, thereby rendering their rejection moot. New claims 5-9 have been drafted in such a way as to correct each of the listed informalities.

Rejection of Claims 1-4 Under 35 U.S.C. § 112, Second Paragraph

Claims 1-4 have been rejected under 35 U.S.C. § 112, second paragraph, for purportedly being indefinite. The Examiner purports that claims 1-4 omit essential steps in the processes claimed. Claims 1-4 have been canceled by the present amendment, thereby rendering their rejection moot. Furthermore, new claims 5-9 have been drafted in such a way as to assure that all the necessary steps are included in the process being claimed.

In light of the above, withdrawal of this rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Rejection of Claims 1 and 2 Under 35 U.S.C. § 102(b)

Claims 1 and 2 have been rejected under 35 U.S.C. § 102(b) for purportedly being anticipated by Delmas et al (*Mol. Endocrinol.* 7:1502-1514 (1993)). For at least all of the reasons set forth below, applicants respectfully request withdrawal of this rejection.

The present invention involves a process for investigating spermatogenesis and monitoring it. This process involves detecting CREM and/or CREM-dependent proteins by using primers for amplifying DNA coding for CREM and/or CREM-dependent

proteins; antibodies against CREM and/or CREM-dependent proteins; and/or DNA encoding for CREM or CREM-dependent proteins. The present inventors unexpectedly found that if CREM is not expressed, or is expressed to a reduced extent but not in a phosphorylated form, the CREM-dependent proteins are not expressed, or are expressed to a reduced extent, and there will be an unbalanced spermatogenesis, resulting in non-functioning spermia.

Delmas et al describe numerous characteristics of CREM. Delmas et al disclose that CREM is expressed only in post-meiotic germ cells and CREM expression is not related with spermatogenesis as CREM expression is found in a mutant mouse in which spermatogenesis is arrested during meiosis, and consequently no haploid spermatogenic cells are produced (see Delmas et al, page 1505, right column, paragraph 3).

Delmas et al do not disclose or suggest that if CREM is not expressed, or is expressed to a reduced extent but not in a phosphorylated form, the CREM-dependent proteins are not expressed, or are expressed to a reduced extent. Furthermore, Delmas et al does not disclose or suggest that such conditions would result in unbalanced spermatogenesis and ultimately non-functioning spermia. Since Delmas et al does not recognize this phenomena, Delmas et al could not possibly disclose or suggest detecting and monitoring the presence of CREM and/or CREM-dependent proteins as a means of investigating and monitoring spermatogenesis in a male animal. Therefore, Delmas et al does not disclose or suggest the present invention.

In light of these remarks, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 102(b).

Rejection of Claims 1-4 Under 35 U.S.C. § 103(a)

Claims 1-4 have been rejected under 35 U.S.C. § 103(a) for purportedly being unpatentable over Delmas et al in view of Stratagene Catalog (1988, page 39) and further in view of Foulke et al (*Nature* 355:80-84 (1992)). For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

Delmas et al is discussed in more detail above, and does not disclose or suggest each of the aspects of the claimed invention. Stratagene Catalog discloses only general aspects of gene kits. Foulke et al disclose only that CREM functional switches from antagonist to activator during spermatogenesis.

Neither the Stratagene Catalog nor Foulke et al disclose or suggest the claimed invention. Specifically, neither the Stratagene Catalog nor Foulke et al disclose or suggest detecting and monitoring the presence of CREM and/or CREM-dependent proteins as a means of investigating and monitoring spermatogenesis in a male animal. Therefore, even if the disclosures of the Stratagene Catalog and Foulke et al were combined with the disclosure of Delmas et al, there would be no suggestion as to a method of detecting and monitoring the presence of CREM and/or CREM-dependent proteins as a means of investigating and monitoring spermatogenesis in a male animal. Thus, applicants believe that the invention as a whole is not *prima facie* obvious.

In light of these remarks, applicants respectfully request withdrawal of this rejection under 35 U.S.C. § 103(a).

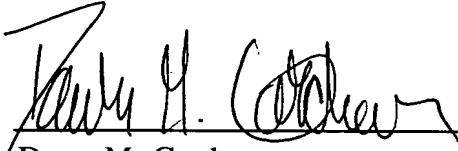
CONCLUSION

From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited.

In the event that there are any questions relating to this application, the Examiner is invited to telephone the undersigned so that prosecution of the subject application may be expedited.

Respectfully submitted,

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